The Pharmacological Basis of Therapeutics, 9th Ed., Hardman *et al.*, eds., McGraw-Hill, New York, NY, 1996, which is incorporated herein by reference). Usually, a daily dosage of WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or functional fragment thereof, can be about 1μg to 100 milligrams per kilogram of body weight. Ordinarily 0.5 to 50, and preferably 1 to 10 milligrams per kilogram per day given in divided doses 1 to 6 times a day or in sustained release form is effective to obtain desired results.

The pharmaceutical compositions according to the present invention may be administered as a single doses or in multiple doses. The pharmaceutical compositions of the present invention may be administered either as individual therapeutic agents or in combination with other therapeutic agents. The treatments of the present invention may be combined with conventional therapies, which may be administered sequentially or simultaneously.

The pharmaceutical compositions comprising WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or functional fragments or derivatives thereof, may be administered by any means that enables the active agent to reach the agent's site of action in the body of the recipient. Because proteins are subject to digestion when administered orally, parenteral administration, *i.e.*, intravenous, subcutaneous, intramuscular, would ordinarily be used to optimize absorption. In addition, the pharmaceutical compositions of the present invention may be injected at a site at or near hyperproliferative growth. For example, administration may be by direct injection into a solid tumor mass or in the tissue directly adjacent thereto. If the individual to be treated is suffering from psoriasis, the WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or functional fragment thereof, may be formulated with a pharmaceutically acceptable topical carrier and the formulation may be administered topically as a creme, lotion or ointment for example.

Vaccine compositions, used for prophylactic or therapeutic treatment against WNV or other viruses including *Flavivirus* or *Pestivirus* infection in an individual, comprising a WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or functional fragment thereof, and a pharmaceutically acceptable carrier or diluent, may be formulated by one of skill in the art with compositions selected depending upon the chosen mode of administration. Suitable pharmaceutical carriers for vaccines are described in *Remington's Pharmaceutical Sciences*, *supra.*, a standard reference text in this field, and can include any carrier that does not itself induce the production of antibodies harmful to the individual receiving the composition. Suitable carriers include large, slowly metabolized macromolecules, such as proteins,

polysaccharides, polylactic acids, polyglycolic acids, polymeric amino acids, amino acid copolymers, and lipid aggregates (such as oil droplets or liposomes). Such carriers are well known to those of ordinary skill in the art. Additionally, these carriers may function as immunostimulating agents ("adjuvants"). Furthermore, the antigen may be conjugated to a bacterial toxoid, such as a toxoid from diphtheria or tetanus.

Adjuvants that can be used with the vaccine compositions of the invention include, but are not limited to, (1) aluminum salts (alum), such as aluminum hydroxide, aluminum phosphate, aluminum sulfate, etc.; (2) oil-in-water emulsion formulations, such as for example, (a) Synthetic Adjuvant Formulation (SAF), available from Chiron (Emeryville, CA), and (b) Ribi Adjuvant System (RAS), (Corixa, Seattle, WA) containing detoxified endotoxin and mycobacterial cell wall components in 2% squalene; (3) water-in-oil formulations such as TiterMax, available from CytRx (Norcross, GA); (4) saponin adjuvants, such as Stimulon (Cambridge Bioscience, Worcester, MA) may be used or particles generated therefrom such as ISCOMS (immune-stimulating complexes); (4) Freund's Complete Adjuvant (FCA) and Freund's Incomplete Adjuvant (FIA); (5) cytokines, such as interleukins (IL-1, IL-2, etc.), macrophage colony stimulating factor (M-CSF), and tumor necrosis factor (TNF), etc; and (6) other substances that act as immunostimulating agents to enhance the immunological effectiveness of the vaccine composition.

Vaccine compositions of the invention typically will contain diluents, such as water, saline, glycerol, ethanol, etc. Additionally, auxiliary substances, such as wetting or emulsifying agents, pH-buffering substances, and the like, may be present in such vehicles.

Vaccine compositions of the invention typically are prepared as injectables, either as liquid solutions or suspensions. Solid formulations, suitable for dissolving in, or suspending in, liquid vehicles prior to injection, may also be prepared. The preparation also may be emulsified or encapsulated in liposomes for enhanced adjuvant effect, as discussed above under pharmaceutically acceptable carriers.

The vaccine compositions of the present invention comprise an immunologically effective amount of WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or functional fragments or derivatives thereof, and may be administered by any means that enables the recipient's immune system to generate a prophylactic or therapeutic immune response. The immunologically effective amount of WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or functional fragments or derivatives thereof, is the quantity administered to an

individual, either in a single dose or as part of a series, that is effective for therapeutic or prophylactic treatment of the individual. This amount varies depending upon the health and physical condition of the individual to be treated, the taxonomic group of individual to be treated (*e.g.*, nonhuman primate, primate, etc.), the capacity of the individual's immune system to synthesize antibodies, the degree of protection desired, the formulation of the vaccine, the treating physician's assessment of the medical situation, and other relevant factors. It is expected that the amount will fall in a relatively broad range that can be determined through routine trials.

A common requirement for any route of administration is efficient and easy delivery. In one embodiment of the invention, the vaccine compositions are administered parenterally, *e.g.*, by injection, either subcutaneous or intramuscular injection. Other means of administration include, but are not limited to, transdermal, transcutaneous, intraperitoneal, mucosal, or general persistent administration. Dosage treatment may be a single dose schedule or a multiple dose schedule. The vaccine may be administered in conjunction with other immunoregulatory agents and/or in conjunction with other vaccines.

Nucleic acid

Another aspect of the present invention relates to pharmaceutical compositions that comprise a nucleic acid molecule that encodes WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or a functional fragment thereof, and a pharmaceutically acceptable carrier or diluent. According to the present invention, genetic material that encodes WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or a functional fragment thereof, is delivered to an individual in an expressible form. The genetic material, DNA or RNA, is taken up by the cells of the individual and expressed. The WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or functional fragment thereof, that is thereby produced can induce the apoptotic death of the hyperproliferating cells. Thus, pharmaceutical compositions comprising genetic material that encodes WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or functional fragment thereof, are useful in the same manner as pharmaceutical compositions comprising WNV or other viruses including *Flavivirus* or *Pestivirus* capsid protein, or functional fragments thereof: for treating an individual having a pathology or condition characterized by or associated with hyperproliferating cells. Pharmaceutical compositions of the present invention are particularly useful for treating cancer characterized by solid tumors.